


SOP 07 A	<div style="text-align: center;">  Sri MANAKULA VINAYAGAR Medical college and Hospital </div>	
SOP code: SOP 07A/ V2.1	Initial Full Board Review of New Research Study Protocols	Effective Date: 15.11.2019

Title: Initial Full Board Review of New Research Study Protocols

Note: New annexure no 2 is added after approval of SMVMCH-EC members. It is amended and will be effective from 15.11.2019

Annexure 2- Study Assessment Form to be used by the Primary Reviewer
(Annexure 02/SOP/7A/V2.1)


Annexure 2: AX 02/SOP 7A/V2.1

Study Assessment Form to be used by the Primary Reviewer

IEC code number of Protocol :		Date (DD/MM/YY):	
Protocol Title :			
Principal Investigator:			
Department :			
No. of Participants:		No. of Study site (s) :	

Mark and comment on whatever items are applicable to the study.


S. No	Item	Comments (if any)
1.	Objectives of the Study <input type="checkbox"/> clear <input type="checkbox"/> unclear	
2	Need for Human Participants <input type="checkbox"/> Yes <input type="checkbox"/> No	
3	Methodology: (comment on sample size) <input type="checkbox"/> clear <input type="checkbox"/> unclear	
4 a.	Background Information and Data <input type="checkbox"/> Sufficient <input type="checkbox"/> Insufficient	
4 b.	Risks and Benefits Assessment <input type="checkbox"/> Acceptable <input type="checkbox"/> Unacceptable	
4 c.	Inclusion Criteria <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	
4 d.	Exclusion Criteria <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate	

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S. No	Item	Comments (if any)
4 e.	Discontinuation and Withdrawal Criteria <input type="checkbox"/> Appropriate <input type="checkbox"/> Inappropriate <input type="checkbox"/> NA	
5	Involvement of Vulnerable Participants: Yes <input type="checkbox"/> No <input type="checkbox"/>	
6	Control Arms (placebo, if any) Yes <input type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>	
7	Contents of the Informed Consent Document: <input type="checkbox"/> clear <input type="checkbox"/> unclear	
8	Language of the Informed Consent Document: <input type="checkbox"/> clear <input type="checkbox"/> unclear	
9	Inducement for Participation Unlikely <input type="checkbox"/> Likely <input type="checkbox"/>	
10	Provision for Compensation for Participation <input type="checkbox"/> Appropriate <input type="checkbox"/> inappropriate <input type="checkbox"/> NA	
11	Provision for Treatment for Study-Related Injuries <input type="checkbox"/> Appropriate <input type="checkbox"/> inappropriate <input type="checkbox"/> NA	

Any other comments:

Reviewer's Signature with date:

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	Name	Designation	Signature
Prepared	Dr. Vimal. M	Member	
	Dr. Nishanthi. A	Member	
Reviewed	Dr. R. N. Kagne	Member Secretary	
	Dr. Amol Dongre	Member	 15/11/19
Approved	Dr. T. Thiagarajan	Chairman	
Issued	Dr. D. Rajagovindan	Director, SMVMCH	

